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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,071

09/25/2003

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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,071

Applicant(s)

MAULT ET AL.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 12, 18, 26, 31, and 33 have been amended. Claims 1-34 are pending.
2. The objections to Drawings are WITHDRAWN in view of the Replacement Drawing Sheets 1-4, filed on 12 February 2007.

Response to Arguments

3. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Specification

4. The disclosure is objected to because of the following informalities:

The patent applications in the "Cross Reference To Related Applications" section of the Specification needs to be updated to indicate issued patents. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8, 11-14, 17-20, 22-28, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel et al, US 3,799,149 A ("Rummel"), in view of Harnoncourt et al, US 5,645,071 A ("Harnoncourt '071").

Claims 1 and 2: Rummel teaches a respiratory gas exchange monitor ("an apparatus for the measurement of metabolic rate and breathing dynamics in which inhaled and exhaled breath are sense", including a computation circuit computing "oxygen consumption, carbon dioxide production, minute volume and respiratory exchange ratio," see Abstract, see figs. 1 and 2) comprising:

a respiratory gas conduit ("mouthpiece") 16 configured to convey inhaled gases and exhaled gases of a subject (see col. 3, ll. 31-40);

a respiratory gas flow meter (combination of "inspiration spirometer" and "expiration spirometer") 12/20 coupled to said respiratory gas conduit 16, said respiratory gas flow meter 12-20 being configured to generate an output associated with

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both a volume of said inhaled gases ("INSP. VOL." Signal, see fig. 1) and a volume of said exhaled gases ("EXP. VOL.", see fig. 1);

a respiratory gas ("mass spectrometer") 28 coupled to said respiratory gas conduit, said respiratory gas sensor being configured to generate an output associated with a concentration of oxygen in said exhaled gases (mass spectrometer outputs "O2" signal, see fig. 1); and

a computation unit ("computer") 38/42/44/50 coupled to said respiratory gas flow meter 12/20 and said respiratory gas sensor 28, said computation unit 42 being configured to process said output of said respiratory gas flow meter and said output of said respiratory gas sensor to determine an amount of carbon dioxide produced by said subject ("[t]he volume of carbon dioxide, CO₂, produced for each respiratory cycle," see col. 8, l. 55, to col. 9, l. 2) and an amount of oxygen consumed by said subject ("the volume of oxygen consumed," see col. 8, ll. 36-53), said computation unit being configured to determine a respiratory quotient of said subject based on said amount of carbon dioxide produced and said amount of oxygen consumed ("resultant quotient Y/Z," see col. 9, ll. 41-55).

Rummel does not explicitly teach a "single respiratory gas flow meter" (see claim 1) wherein "said respiratory gas flow meter is an ultrasonic flow meter" (see claim 2). However, Harnoncourt '071 teaches a computation unit (monitoring unit) II coupled to the "sensor head" I, wherein the "sensor head I" (see figs. 1 and 2), comprising: a respiratory gas conduit (not labeled, between "connectors" 6 and 7); a single respiratory gas flow meter ("continuous flow measuring device," see col. 4, ll. 35-37), which is a

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ultrasonic flow meter (ultrasonic receive elements, see col. 4, ll. 40-45) S2; a respiratory oxygen sensor (see col. 2, ll. 41-48, and col. 7, ll. 17-29). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel's inspiration and expiration spirometers 12/20 to ultrasonic transmit-receive elements S1/S2 taught by Harnoncourt '071 because Harnoncourt '071 explicitly discloses that the Harnoncourt '071 device is used "for the determination of physiologically relevant pulmonary function parameters" (see col. 4, ll. 36-40).

Claims 3 and 4: Rummel teaches the respiratory gas sensor 28 is an oxygen sensor (mass spectrometer outputs oxygen concentration), and the output of the respiratory gas sensor 28 is associated with a concentration of oxygen in inhaled gases (see col. 8, ll. 40-50).

Claims 5-8: Rummel teaches the computation unit 38/42/44/50 configured to process the outputs of the respiratory gas flow meter and the respiratory gas sensor to determine the concentration of oxygen in the exhaled gases (see col. 8, ll. 36-40), to determine the amount of carbon dioxide produced and the amount of oxygen consumed based on the inhaled volume, exhaled volume, exhaled oxygen concentration, inhaled oxygen concentration, and ambient oxygen concentration (see col. 8, l. 35, to col. 9, l. 2), and to determine the respiratory quotient based on a ratio ("resultant quotient Y/Z") based on a ratio of the carbon dioxide produced and oxygen consumption (see col. 9, ll. 41-47).

Claim 11: Rummel teaches a display unit 46 coupled to the computation unit 38/42/44/50 (see fig. 1).

Claims 12, 13, 18, 19: Rummel in view of Harnoncourt '071 teaches the claimed respiratory gas exchange monitor, comprising a single respiratory gas flow meter, a respiratory gas sensor, a computation unit, and a respiratory gas conduit, as discussed above in claims 1 and 5-8.

Claims 14, 17, 20, and 25: Rummel teaches the respiratory gas conduit 16 is a flow tube ("mouthpiece"), and a display unit 46 configured to provide indicia of the respiratory quotient ("CO₂/O₂ ratio", see col. 3, ll. 24-27).

Claims 22-24: Rummel teaches the computation unit 38/42/44/50 configured to determine a mass of carbon dioxide and oxygen in the exhaled gases based on the mass of the exhaled gases and a mass of nitrogen in the exhaled gases, to determine the mass of nitrogen in the exhaled gas based on a concentration of nitrogen in ambient air, and to determine a concentration of exhaled oxygen, amount of carbon dioxide produced, and amount of oxygen consumption (see col. 7, l. 53, to col. 8, l.10, and col. 8, l. 36, to col. 9, l. 2).

Claim 26: Rummel in view of Harnoncourt '071 teaches the claimed respiratory gas exchange monitor, comprising a conduit, a first sensor, a second sensor, and a computation unit, as discussed above in claim 1, with reference to a respiratory conduit, a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claims 27 and 28: Rummel teaches the claimed flow tube and ultrasonic flow meter as discussed above in claims 14 and 2.

Claim 31: Rummel in view of Harnoncourt '071 teaches the claimed respiratory gas exchange monitor, comprising integral sensor means for determining both a volume of inhaled gases of a subject, means for determining a concentration of oxygen in said exhaled gases, means for determining an amount of carbon dioxide produced and an amount of oxygen consumed, and means for determining a respiratory quotient, as discussed above in claim 1, with reference to a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claim 32: Rummel teaches a respiratory gas exchange monitor, said respiratory gas exchange monitor being configured to perform a method comprising:

determining a volume of inhaled gases and a volume of exhaled gases (see col. 6, ll. 5-8); and

determining a respiratory quotient ("resultant quotient Y/Z ,") based on said amount of carbon dioxide produced and said amount of oxygen consumed (see col. 9, ll. 41-55).

Rummel does not teach "determining a speed of sound in said exhaled gases," and "determining an amount of carbon dioxide produced and an amount of oxygen consumed based on said volume of said inhaled gases, said volume of said exhaled gases, and said speed of sound in said exhaled gases." However, Harnoncourt '071 teaches an "ultrasonic [receive] element" S2 for determining the speed of sound in the exhaled gases (see "the transit times of the sonic pulses are also employed for

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calculation of the flow velocities of the gas or gas mixture, whose molar mass is determined,” col. 1, ll. 51-59, and claim 4), and a “monitoring unit II” capable of determining oxygen consumption (“oxygen uptake”), carbon dioxide produced (“CO₂ release”), and respiratory quotient (“respiratory coefficient”) (see col. 2, ll. 15-21, and col. 6, ll. 28-35). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel’s inspiration and expiration spirometers 12/20 to ultrasonic transmit-receive elements S1/S2 taught by Harnoncourt ‘071 because Harnoncourt ‘071 explicitly discloses that the Harnoncourt ‘071 device is used “for the determination of physiologically relevant pulmonary function parameters” (see col. 4, ll. 36-40).

Claim 33: Rummel in view of Harnoncourt ‘071 teaches the claimed method of determining a respiratory quotient of a subject, comprising the steps of: determining a volume of inhaled gases of said subject and a volume of exhaled gases of the subject in a single gas flow meter; determining a mass of carbon dioxide and oxygen in said exhaled gases; determining a concentration of oxygen in said exhaled gases based on said mass of carbon dioxide and oxygen in said exhaled gases; determining an amount of carbon dioxide produced by said subject and an amount of oxygen consumed by said subject based on said volume of said inhaled gases, said volume of said exhaled gases, and said concentration of oxygen in said exhaled gases; and determining a respiratory quotient of said subject based on said amount of carbon dioxide produced and said amount of oxygen consumed, as discussed above in claim 1, with reference to the

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respiratory gas exchange monitor, comprising a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claim 34: Rummel teaches determining a mass of said exhaled gases (see col. 7, l. 53, to col. 8, l. 10), determining a mass of nitrogen in said exhaled gases (see col. 7, ll. 62-66), and determining said mass of carbon dioxide and oxygen in said exhaled gases based on said mass of said exhaled gases and said mass of nitrogen in said exhaled gases (see col. 9, ll. 5-61).

6. Claims 15, 16, 21, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel in view of Harnoncourt '071, as applied to claims 12, 18, and 26 above, and further in view of over Harnoncourt et al, US 5,503,151 A ("Harnoncourt '151").

Claims 15, 16, 21, and 29: Rummel in view of Harnoncourt '071 does not teach the respiratory gas flow meter includes "a plurality of ultrasonic transducers" and the respiratory gas sensor, or second sensor, is "a fluorescence quench oxygen sensor." However, Harnoncourt '151 teaches a respiratory gas exchange monitor ("an apparatus for measuring the parameters of respiratory gases," see Abstract) 10, comprising: a plurality of ultrasonic transducers (ultrasonic sensor for measuring "respiratory volumetric flow rate," see col. 3, l. 37) 22; and a fluorescence quench oxygen sensor ("optical sensor," which uses "luminescence or fluorescence measurements [to determine] the oxygen concentration," see col. 2, ll. 3-16 and 46-57, col. 3, ll. 1-6, and col. 4, ll. 3-15) 28. Therefore, it would have been obvious for one of ordinary skill in the

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art at the time the invention was made to modify Rummel in view of Harnoncourt '071 to include ultrasonic transducers and a fluorescent optical oxygen sensor because Harnoncourt '151 suggests that it is possible to determine respiratory volumes, respiratory frequency, oxygen uptake, release of CO₂ and the concentration of anesthetic gases using the Harnoncourt '151 device (see col. 4, ll. 16-30), which are the determined respiratory parameters of the Rummel device. In addition, Harnoncourt '151 discloses that an advantage to patented device is that it "renders possible a particularly compact design" (see col. 2, ll. 3-16).

7. Claims 9, 10, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel in view of Harnoncourt '071, as applied to claims 1 and 26 above, and further in view of Labuda et al, US 6,325,978 B1 ("Labuda").

Claims 9, 10, and 30: Rummel in view of Harnoncourt '071 does not teach the computation unit is configured to "compare said respiratory quotient with a reference respiratory quotient to determine a measure of deviation of said respiratory quotient with respect to said reference respiratory quotient" (claims 9 and 30), and to "determine said reference respiratory quotient based on a nutrient intake of said subject" (claim 10).

However, Labuda teaches the following:

A metabolic measurement (calorimetry) includes determination of a patient's energy requirements (in calories per day) and respiratory quotient (RQ). Interest in the measurement of caloric requirements has closely paralleled the development of nutritional support. For example, the ability to intravenously provide all the necessary nutrition to critically ill patients has only been accomplished within the last 25 years. Along with the realization that we need to feed patients, has come the need to know how much to feed them, what kind of nutrients (carbohydrates, lipids, protein)

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to feed them, and in what ratio the nutrients need to be supplied. The only true way to measure the caloric requirements of patients and to provide a non-invasive quality assessment of their response to nutrition is with indirect calorimetry. Airway O.sub.2 consumption and CO.sub.2 production can be measured non-invasively and provide a basis for the computations needed for a measurement of indirect calorimetry, a direct measurement of the metabolic status of the patient, and the patients' respiratory quotient...

5. When combined with a volume flow device (e.g. a pneumotach), VO.sub.2 (oxygen consumption) can be determined. Oxygen consumption is a very useful parameter in determining (a) oxygen uptake during ventilation or exercise, (b) respiratory exchange ratio or RQ (respiratory quotient) and (c) general patient metabolic status.

See col. 2, l. 54, to col. 3, l. 5, and col. 5, ll. 54-59. Thus, determining a patient's metabolic status, i.e. quality assessment of a patient's response to nutrition using indirect calorimetry, requires an assessment of the patient's caloric intake due to nutrition and the patient's respiratory quotient. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel's computation unit 38/42/44/50 to determining the patient's metabolic measurement, or calorimetry, based on the patient's energy requirement and respiratory quotient as defined by Labuda because this determination is within the scope of Rummel's objective of providing a system which "enables the accurate measurement of metabolic rates and breathing dynamics in varying environments and for subjects undergoing varying degrees of exertion" (see Rummel, col. 1, ll. 51-56).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stanley et al, US 3,725,658 A, teaches an apparatus and method for continuously detecting oxygen in a gas stream, comprising a fluorescent quench oxygen sensor (see fig. 1 and Abstract). Thus, this Rummel in view Stanley is another example of the unpatentability of the limitation "a respiratory gas exchange monitor wherein the respiratory gas sensor is a fluorescence quench oxygen sensor" and contradicts Applicant's arguments, on top of pg. 11 of Remarks, filed on 12 February 2007, that a respiratory gas exchange monitor with a fluorescence quench oxygen sensor is patentable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Navin Natnithithadha
Patent Examiner
Art Unit 3735